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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,441	03/28/2001	Thomas H. Campbell	21120-303	6655

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EXAMINER

NGUYEN, HUONG Q

ART UNIT	PAPER NUMBER
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3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/21/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/820,441

Applicant(s)

CAMPBELL ET AL.

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-44 is/are pending in the application.
- 4a) Of the above claim(s) 43 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/5/2005, 12/4/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of invention I in the reply filed on 6/12/2006 is acknowledged. The traversal is on the ground(s) that it would be not be burdensome to examine all claims. This is not found persuasive because the inventions are distinct as explained in the previous restriction requirement, thus necessitating different searches, which would provide a burden.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 8/5/2005 and 12/04/2006 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the ultrasonic imaging arrangement of **Claims 29-32, 36, and 39-41** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet,

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even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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5. **Claim 25** is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claim 5 of U.S. Patent No. 6245026. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the claim of the present invention and the claim in question is a control circuit, and as said patent already discloses a display device arranged to receive signals from the thermal sensors (Col.19: 37-38), it is therefore obvious that a control circuit would also be present along with the display to receive the thermal signs and process them for display.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **Claims 29-32 and 41** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the specification and drawings fail to clearly disclose the relative positioning of an ultrasonic imaging arrangement including a rotatable ultrasonic imaging transducer coupled to a rotatable shaft in regards to the elongated member. This is further emphasized by the lack of drawings to illustrate said element, as evidenced by the drawing objections above.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. **Claim 25-27 and 33-34** are rejected under 35 U.S.C. 102(e) as being anticipated by Tachibana et al (US Pat No. 6176842).

10. In regards to **Claim 25**, Tachibana et al disclose a system for thermally mapping a vessel wall in the body of a patient comprising:

an elongated member (14) suitable for insertion in a vessel of a body of a patient, the elongated member having a proximal and a distal end;

an expansion device (12, 30) disposed at or about the distal end of the elongated member;

at least one thermal sensor (22) capable of detecting relatively small temperature variations on the vessel wall, the at least one thermal sensor disposed on the expansion device wherein the expansion device is thereby capable of positioning the at least one thermal sensor against the vessel wall;

a control circuitry (100) which receives and processes signals from the at least one thermal sensor;

a display (102) coupled to the control circuitry and arranged to receive information from the thermal sensor and to graphically display a thermal map showing temperature variations along a portion of the vessel wall, best seen in Figure 16 (Col.25: 10-16).

11. In regards to **Claim 26**, Tachibana et al disclose the at least one thermal sensor (22) comprises a plurality of thermal sensors arranged in a band disposed about the distal section of the elongate shaft, best seen in Figure 1B.

12. In regards to **Claim 27**, Tachibana et al disclose the at least one thermal sensor is selected from the group consisting of an infrared sensor, a thermocouple, and a thermistor (Col.24: 30-35).

13. In regards to **Claim 33**, Tachibana et al disclose at least a first flow altering member (30a) on the elongated member adjacent the at least one thermal sensor (22), best seen in Figure 8.

14. In regards to **Claim 34**, Tachibana et al disclose at least a second flow altering member (30b) on the elongated member adjacent the at least one thermal sensor (22), the at least one thermal sensor being positioned on the elongated member between the first flow altering member (30a) and the second flow altering member, best seen in Figure 8.

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15. **Claim 25-27 and 35** are rejected under 35 U.S.C. 102(b) as being anticipated by Stern et al (US Pat No. 5443470).

16. In regards to **Claim 25**, Stern et al disclose a system for thermally mapping a vessel wall in the body of a patient comprising:

an elongated member (16) suitable for insertion in a vessel of a body of a patient, the elongated member having a proximal and a distal end;

an expansion device (14, 39) disposed at or about the distal end of the elongated member;

at least one thermal sensor (24, 42) capable of detecting relatively small temperature variations on the vessel wall, the at least one thermal sensor disposed on the expansion device wherein the expansion device is thereby capable of positioning the at least one thermal sensor against the vessel wall (Col.4: 59-60);

a control circuitry (128) which receives and processes signals from the at least one thermal sensor;

a display included with computer (114) coupled to the control circuitry and arranged to receive information from the thermal sensor and capable of graphically display a thermal map showing temperature variations along a portion of the vessel wall, best seen in Figure 5 and 12.

17. In regards to **Claim 26**, Stern et al disclose the at least one thermal sensor (24, 42) comprises a plurality of thermal sensors arranged in a band disposed about the distal section of the elongate shaft, best seen in Figure 1 and 4.

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18. In regards to **Claim 27**, Stern et al disclose the at least one thermal sensor (24, 42) is selected from the group consisting of an infrared sensor, a thermocouple, and a thermistor (Col.4: 62-66).

19. In regards to **Claim 35**, Stern et al disclose the expansion device (14, 39) is a radially expansible balloon.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. **Claims 29-32 and 36-42** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al in view of Pomeranz (US Pat No. 5558093).

22. Stern et al disclose the apparatus described above but do not disclose said system including an ultrasonic imaging arrangement. However, Stern et al do disclose said device usable with an imaging apparatus to aid in the device placement (Col.2: 61-64). Pomeranz teaches of an ultrasonic imaging arrangement comprising a rotatable ultrasonic transducer (32, 64) coupled to a rotatable shaft (24, 54) that extends proximally as an effective imaging device and can be used with other devices analogous to the invention of Stern et al (Col.7: 44-45). Pomeranz also discloses said imaging apparatus comprising a control circuit (102) to receive

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signals from said imaging apparatus and a display (108) coupled to said control circuit to display an image of what is scanned (Col.5: 3-5, 40-42), as disclosed in US Pat No.4794931, incorporated by reference by Pomeranz (Col.6: 63-64).

23. Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Stern et al to include an ultrasonic imaging arrangement usable with devices analogous to Stern et al, comprising a rotatable ultrasonic transducer coupled to a rotatable shaft that extends proximally, as taught by Pomeranz, such that in combination, the at least one thermal sensor and the ultrasonic imaging arrangement are disposed adjacent each other and said control circuit processes both a thermal signal and an imaging signal to display both to show a thermal map, to improve the invention of Stern et al by including an effective imaging device to enable positioning and as well as subsequent imaging along with the device of Stern et al.

24. **Claims 28** is rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al in view of vanHooydonk (US Pat No. 5902251).

25. Stern et al disclose the invention above but do not disclose said display shows a color coded thermal map. VanHooydonk disclose an analogous apparatus comprising a display that graphically displays a thermal map from thermal sensors color coded such that temperature of tissue is indicated by the color on the display as an effective method to communicate the thermal data (Col.16: 42-47). Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Stern et al so that the graphical display of the thermal map is color coded such that temperature of tissue graphically displayed is indicated by the color of the tissue on the display as an effective means to relay said thermal information.

Response to Arguments

26. Applicant's arguments filed 8/5/2005 have been fully considered but they are not persuasive. Applicant contends that Tachibana et al does not disclose being capable of detecting relatively small temperature variations nor is the system disclosed as being capable of displaying a thermal map. Examiner notes that as Tachibana et al already disclose a thermal sensor structure, said sensor is said to be capable of detecting relatively small temperature variations as recited in the intended use. Examiner also notes that Tachibana et al do disclose a display and control circuit used to relay the thermal information and thus are capable of displaying a thermal map, as explained in the above rejection.

Conclusion

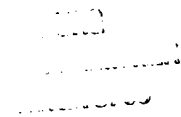
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN
12/11/2006

A handwritten signature in black ink, appearing to be 'JEN'.A handwritten signature in black ink, appearing to be 'McKendry'.Faint handwritten text, possibly a date or initials, located below the signature.